Music therapy during skin-breaking procedures in infants admitted to a Neonatal Intensive Care Unit or High Care ward: a non-pharmacological intervention

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON56924

Source
ToetsingOnline

Brief title
Music therapy during skin-breaking procedures

Condition

- Neonatal and perinatal conditions

Synonym
Pain, stress

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Music therapy, Neonatology, Skin-breaking procedures

Outcome measures

Primary outcome

Our primary outcome is the direct pain response, measured using the Preterm Infant Pain Profile - Revised (PIPP-R).

Secondary outcome

Secondary outcomes will be heart rate variability (HRV), cerebral oxygen saturation using near-infrared spectroscopy (NIRS), changes in cortical activity measured using amplitude-integrated EEG, General Movements Optimality Scores, and our in depth musical micro-analysis and parental/staff perspectives on music therapy as procedural support.

Study description

Background summary

Neonates admitted to a Neonatal Intensive Care Unit (NICU) or a high care (HC) ward experience a highly different environment compared with the maternal womb. Although this environment is lifesaving, it involves a variety of stressors, such as painful procedures that may have long-lasting consequences after discharge. Mechanisms through which these long-term consequences occur are proposed to be altered hypothalamic-pituitary-adrenal (HPA) axis development, responsible for the stress regulation in the body through cortisol production, and a direct effect on brain development. While pharmacological analgesia has been implemented, non-pharmacological options have also been suggested to reduce pain, among which music therapy. Specifically in a NICU and HC setting, music therapy is a promising and novel intervention that may counteract or

attenuate the altered stress response through creating a possible link to in-utero exposure to musical sounds (i.e., rhythmic heartbeat, maternal voice, or music listened to by the mother). Music therapy regards the use of live-performed musical interventions by a certified neonatal music therapist, and it is tailored to the needs of the individual infant and their parents.
With our study, we aim to investigate the effects of music therapy during skin-breaking procedures in neonates admitted to a NICU or HC ward on the pain and stress response.

Study objective

The objectives of the study are to:
A. Determine the effects of music therapy during skin-breaking procedures on the pain response in infants admitted to a NICU or HC ward.
B. Determine the effects of music therapy during skin-breaking procedures on the autonomic nervous system regulation in infants admitted to a NICU or HC ward.
C. Further clarify the mechanism of music therapy in regulating pain response and autonomic nervous system response by performing a micro-analysis of the music played in concordance with responses by infants.
D. To evaluate parental perspectives on music therapy during skin-breaking procedures.

Study design

A randomized controlled cross-over study including 75 infants.

Intervention

The intervention will be a sedative live-performed music therapy session according to the Rhythm, Breath and Lullaby method. This protocol is currently standard care in several centers, including the NICU of the UMCG, but at present not used for procedural support. The UMCG NICU employs two board-certified music therapists with the additional Rhythm, Breath and Lullaby specialization. The intervention will commence before the painful procedure and will be continued after the painful procedure is finished, to cover the full procedure.

Study burden and risks

Data for this study cannot be obtained in another population, as the intention is to study the live-music for procedural support in infants. As this intervention may be pain relieving, stress reducing and improving neurodevelopment, it is worthwhile to study. We believe that the burden and risks associated with the participation in this pilot study are small to

non-existent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Neonates admitted to a NICU or a HC ward:
- If the gestational age is between 33 and 42 weeks, expected length of stay >2 weeks
- If the gestational age is <32 weeks, expected length of stay > 3 weeks (because one of our research projects has shown that starting music therapy after 7 days is more beneficial for these children than starting before 7 days of life)
- Need for repeated skin-breaking procedures (at least three) within the study period

- Written informed consent from parents

Exclusion criteria

- Inability of the parents to understand/speak Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-07-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86317.042.24